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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/340,664	11/16/1994	KAARE M. GAUTVIK	FORSK3.0001	5529

7590 02/11/2004

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EXAMINER	
SPECTOR, LORRAINE	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/11/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/340,664	Applicant(s) GAUTVIK ET AL.	
	Examiner Lorraine Spector, Ph.D.	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 31-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 31-35 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

Part III: Detailed Office Action:

Pursuant to the decision by the Board of Patent Appeals and Interferences (BPAI), dated 02 July 2003, prosecution is reopened.

Request for Information:

Applicant and the assignee of this application are required under 37 CFR §1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

As noted by the BPAI at page 12 of the decision of 7/2/2003, the specification at page 7 teaches the use of an hPTH standard (1-84) to compare and assess the results of the purification process. The specification teaches that the purification product eluted in the same peak as this standard and co migrated with the standard as one band on a gel. The specification implicitly asserts that these comparisons demonstrate the purity and completeness of the protein being claimed. Accordingly, applicants are requested to provide all pertinent information regarding the source of the protein used as a standard.

In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure.

The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or

cannot be readily obtained will be accepted as a complete reply to the requirement for that item.

A complete reply to this Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the Office action.

Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially homogeneous" in claims 31-35 is a relative term which renders the claims indefinite. The term "substantially homogeneous" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Rejections over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 31 and 32 are rejected under 35 U.S.C. § 102(b) as anticipated by Brewer et al., U.S. Patent Number 3,886,132 as set forth in the Examiner Answer mailed 7/28/2000, and as affirmed by the Board of Patent Appeals and Interferences (BPAI) in the decision mailed July 2, 2003.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made. Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 33-35 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Brewer et al., U.S. Patent Number 3,886,132 as set forth in the Examiner Answer mailed 7/28/2000.

Claims 33-35 are drafted in product-by-process format. A product-by-process limitation is given weight to the extent that it dictates the structure or nature of the product obtained. In this case, the product-by-process limitations are drawn to recombinant production of the claimed "substantially homogeneous hPTH(1-84)". "hPTH(1-84) as a substantially homogeneous protein", as claimed in claim 31, has been found anticipated by Brewer et al., as affirmed by the BPAI. As stated by the BPAI,

> "absent evidence to the contrary, a reference that anticipates, or renders obvious claim 31, would also anticipate, or render obvious claims 33-35. We remind the examiner and appellants that the determination of patentability in product-by-process claims is based on product itself, even though such claims are limited and defined by a process. in re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). "[W]here a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product." In re Best, 562 F. 2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 710 F.2d 799, 803, 218 USPQ 289, 292-293 (Fed. Cir. 1983)."

In this case, the protein as produced recombinantly, as recited in the claims, would reasonably be expected to be indistinguishable from the product as purified from nature, as disclosed by Brewer. As previously stated, and as affirmed by the BPAI, based upon Brewer's ability to sequence 34 residues of the purified protein, the protein of Brewer appears to have been at least as "substantially homogeneous" as that obtained by applicants. It is further noted, also as pointed out by the BPAI, that the specification does not define the term "substantially homogeneous".

Claims 31-35 are rejected under 35 U.S.C. 102 (a), (b) and/or (f) as being anticipated by applicants admission of the prior art.

As noted by the BPAI at page 12 of the decision of 7/2/2003, the specification at page 7 teaches the use of an hPTH standard (1-84) to compare and assess the results of the purification process. The specification teaches that the purification product eluted in the same peak as this standard and comigrated with the standard as one band on a gel. The specification implicitly asserts that these comparisons demonstrate the purity and completeness of the protein being claimed. In order for the "standard" to have been useful for such comparison, it itself must have met the limitations of the pending claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31-35 are rejected under 35 U.S.C. § 103 as being unpatentable over Breyel et al. (3rd Eur. Cong. Biotech., cited by appellants) or Mayer et al. (EP 0 139 076, cited by appellants), any reference of the three in view of Kaisha et al. (GB 2 092 596, cited by appellants), and Brewer et al., U.S. Patent Number 3,886,132.

Breyel et al. teach expression of mature hPTH in *E. coli*, see Summary, page 363. The protein was expressed and bacterial cell extracts assayed for activity, see page 366 for example. Breyel differs from the instant claims only in that the protein was not purified from the bacterial cell extracts.

Mayer et al. teach recombinant production of hPTH in *E. coli*, see page 9, first full paragraph for example, page 12 of the enclosed English-language translation. The protein was purified from the cells and shown to be biologically active. Mayer et al. do not teach purification to the degree recited in the rejected claims.

Kaisha et al. teach a process for the production of hPTH. Although their patent is not drawn to recombinant production using bacterial or yeast cells, they disclose at page 2, first column, beginning at line 55 that:

> "The hPTH thus obtained can be collected easily by purification and separation techniques using conventional procedures such as salting-out, dialysis, filtration, centrifugation, concentration and lyophilisation. If a more highly purified hPTH preparation is desirable, a preparation of the

highest purity can be obtained by the above-mentioned techniques in combination with other conventional procedures such as adsorption and desorption with ion exchange, gel filtration, affinity chromatography, isoelectric point fractionation and electrophoresis."

Thus, Kaisha et al. teach the desirability of making large quantities of hPTH, and that the person of ordinary skill in the art, given a preparation containing hPTH, would be able to devise a protocol for purifying such with a reasonable expectation of success and without undue experimentation.

Brewer et al. specifically teach a protocol for purifying hPTH from its natural source, parathyroid tissue, see column 2, lines 3-13. As stated in the rejection under 35 U.S.C. §102(b) and affirmed by the BPAI, the hPTH so purified meets the purity limitations of the claims.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to express hPTH as taught by Breyel et al. or Mayer et al., and then to purify the hPTH so produced as suggested by Kaisha et al., such as using the protocol of Brewer et al. to obtain highly purified hPTH. The ordinary artisan would have been motivated to do so in view of the art recognized desirability of obtaining hPTH in pure form, as evidenced by all four cited references. As both Breyel and Mayer obtained at least partially purified preparations, the person of ordinary skill in the art would have recognized that such preparations could be further purified using the protocol of Brewer et al. The teachings of Brewer et al. indicate that the ordinary artisan would have had at least a reasonable expectation of success at purifying hPTH once produced as taught and/or suggested by Breyel or Mayer. Accordingly, the claimed invention, taken as a whole, is *prima facie* obvious over the cited prior art.

Conclusion:

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number is 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz. ***Effective 1/21/2004, Dr. Kunz' telephone number is 571-272-0887.***

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Lorraine Spector, Ph.D.
Primary Examiner

08/340664
2/9/2004

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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